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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,367	12/22/2003	Mahendra R. Patel	4-33515P1	7967
72554	7590	08/11/2010	EXAMINER	
SANDOZ INC 506 CARNEFIE CENTER PRINCETON, NJ 08540			WARD, PAUL V	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			08/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/743,367	Applicant(s) PATEL ET AL.	
	Examiner PAUL V. WARD	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14, 18 and 19 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/26/07 9/3/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election, with traverse, of Group I in the reply filed on June 10, 2010 is acknowledged. . The traversal is on the ground that groups I-III are inter-related (i.e., part of one and the same invention), and thus, would not be unduly burdensome. This is not found persuasive because Groups I-III are separate and patentably distinct because there is no patentable co-action among them. Applicant's inventions are distinct and have acquired a separate status in the art due to their recognized divergent subject matter and different classification. Additionally, because each group has different subclasses, it would constitute a burden on the Examiner to search all subclasses. Further, different fields of search would be required in the non-patent literature. Moreover, the process for using the product can be practiced with another materially different product. Thus, Applicant's inventions are distinct and have acquired a separate status in the art due to their recognized divergent subject matter and different classification. A search of the three groups would impose an undue burden upon the Examiner. Therefore, the restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

Groups II-III are withdrawn from further consideration pursuant to 37 CFR 1.152(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant reserved the right to file a divisional application to the non-elected subject matter.

Applicant is entitled to have the method claims, which are commensurate in scope with the elected invention, rejoined, since the compositions in Group I are allowed. An amendment, which results in the process and method claims (Groups II and III) being commensurate in scope with the allowed claims, will be welcomed.

An action on the merits of Group I (claims 1-14 and 18-19) is contained herein.

REJOINDER

NOTE: Examiner notes that dependent claims 16 and 17 are method claims that refers to claim 15, which is a process claim. Examiner suggests that claims 16 and 17 be amended to read "The process according to Claim 15..."

Claims 1-14 and 18-19 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 15-17 and 20, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, may be rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 can be rejoined, **the restriction requirement as set forth in the Office action mailed on May 13, 2010 is will be withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the

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provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Allowable Subject Matter

Claims 1-14 and 18-19 are allowed. The compositions in Group I (claims 1-14 and 18-19) were not found to be obvious or anticipated by the prior art of record. The prior art does not teach or suggest the compositions comprising a hydrophilic and water-soluble polymer wherein the hydrophilic and water-soluble polymer is present in an amount great than 10 weight percent of the composition as claimed by the Applicant.

Conclusion

This application is in condition for allowance except for the presence of non-elected claims.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/PAUL V WARD/

Examiner, Art Unit 1624